DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Purged
HFI-35 415

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(617)279-1675 FAX: (617)279-1742

WARNING LETTER

September 8, 1997

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NWE-15-97W

Vincent J. McCorkle, President & CEO
Mercy Hospital Blood Bank
299 Carew Street
Springfield, MA 01102

Dear Mr. McCorkle:

During an inspection of Mercy Hospital Blood Bank on July 29, 1997, and from our review of your Error/Accident Report dated July 23, 1997, our investigator documented violations of Section 501 (a) (2) (B) of the Federal Food, Drug, and Cosmetic Act and Title 21 of the Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

> Failure to review all records pertinent to a unit of blood or blood component prior to the release or distribution of the final product [21 CFR 606.100 (c)] in that unit 04LK30713 was reported to be initially reactive (i.e., HAG was Blank) yet you processed, labeled and transfused Red Blood Cells (RBC's) and shipped the recovered plasma in interstate commerce.
>
> The Accident Error Report states a "blank space was present where the result should have appeared" but both the ARC Report and your SOP address blanks.
>
> The ARC Work Sheet states that a blank means "initially reactive/skipped, to be retested next day; to be retested next day; or not ordered". Your own SOP (Part III, d) states "Quarantine all components of any units with positive, HLD, Blanks, Ele, or High test results".

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility, as President, to assure that your establishment is in compliance with all requirements of the Federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to E. Frank Gesing, Compliance Officer, U. S. Food and Drug Administration, New England District Office, One Montvale Avenue, Stoneham, MA 02180.

Sincerely,

John R. Marzilli
District Director
New England District

cc: Lewis G. Lefler, MD
Blood Bank Medical Director
Mercy Hospital Blood Bank
299 Carew Street
Springfield, MA 01102